IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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PUBLIC VERSION

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)))	Civil Action No. 05-356-SLR (consolidated)

OPENING MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER

Plaintiffs Janssen L.P., Janssen Pharmaceutica N.V., and Synaptech, Inc. (collectively, "Plaintiffs") submit this memorandum in support of their Motion for a Temporary Restraining Order preventing Defendants from marketing and selling generic versions of Plaintiffs' product RAZADYNE®, a prescription drug covered by U.S. Patent No. 4,663,318 ("the 318 Patent") prior to this Court's decision in this matter. At least one Defendant has indicated that it intends to enter the market once the 30-month stay expires, even if the Court has not yet issued its decision. Accordingly, unless the Court grants the requested relief, Plaintiffs will suffer irreparable harm for which no adequate remedy at law exists.

INTRODUCTION

Between April 22, 2005 and May 17, 2005, seven companies[1] submitted to the FDA Abbreviated New Drug Applications ("ANDA") and certifications under 21

[1] The seven companies included (1) Alphapharm Pty, Ltd.; (2) Barr Laboratories, Inc., a wholly-owned subsidiary of Barr Pharmaceuticals, Inc.; (3) Dr. Reddy's Laboratories, Inc., a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd.; (4) Mylan Pharmaceuticals, Inc., a wholly-owned subsidiary of Mylan Laboratories, Inc.; (5) Par Pharmaceutical, Inc.; (6) Purepac Pharmaceutical, Inc., a wholly-owned subsidiary of Alpharma, Inc. at the time of filing the ANDA (although the generic pharmaceutical business of Alpharma was later acquired by Actavis Group); and (7) Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. With the exception of Par Pharmaceutical, which later switched from a Paragraph IV certification to a Paragraph III certification, these companies are collectively

U.S.C. § 355(j)(2)(A)(vii)(IV) (so-called "Paragraph IV certifications"), seeking approval to manufacture, market and sell a generic version of Plaintiffs' RAZADYNE® product before the expiration of the '318 patent. Plaintiffs sued each of the seven companies for infringement of the '318 patent and all seven cases were consolidated on October 21, 2005. On December 2, 2005, each Defendant stipulated that the commercial use or sale of the drug products described in their ANDAs would infringe claims 1 and 4 of the '318 patent if the patent is valid and enforceable. (D.I. 49). During the next several months, the proceedings against Purepac and its then-parent Alpharma,[2] Dr. Reddy's, Mylan and Teva were stayed and those Defendants agreed to be bound by the decision of the trial court. (D.I. 177, 236, 258, 298) The case against Par was dismissed after it withdrew its Paragraph IV certification in favor of a Paragraph III certification. (D.I. 186) Accordingly, the only two Defendants that actively litigated the case through trial were Barr and Alphapharm.

A bench trial on the merits took place during the week of May 21, 2007. As a result of Defendants' stipulations regarding infringement, the only issues that remained at trial were validity of the '318 patent and whether this was an exceptional case.

Because Plaintiffs filed suit against the Defendants within 45 days of receiving each Paragraph IV certification, they are entitled to an automatic 30-month stay of approval of each ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Prior to the expiration of this stay, Defendants are prohibited from marketing or selling their generic versions of RAZADYNE®. The stay is currently scheduled to expire at 11:59 p.m. on August 27,

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referred to as "Defendants." Another ten companies filed Paragraph III certifications. Thus eleven of the seventeen ANDA filers elected not to challenge the '318 patent.

[2] Actavis Group was later substituted as a party.

2008. Assuming the FDA approves the ANDAs upon expiration of the stay, each Defendant can launch at-risk as of 12:01 a.m. on August 28, 2008 unless the Court issues a decision prior to that time. At least one Defendant has informed Plaintiffs that it intends to do so. Accordingly, a temporary restraining order is necessary to prevent such at-risk launches until the Court is able to complete work on its opinion on the merits.

ARGUMENT

The standards for a temporary restraining order, which are the same as for a preliminary injunction, are well-established in this Circuit:

> (1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary injunctive relief will result in even greater harm to the non-moving party; and (4) whether granting the preliminary relief will be in the public interest.

Allegheny Energy, Inc. v. *DQE, Inc.*, 171 F.3d 153, 158 (3d Cir. 1999); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1374 (Fed. Cir. 2006); *Nutrasweet Co. v. Vit-Mar Enterprises, Inc.*, 112 F.3d 689, 692-93 (3d Cir. 1997) (standard for temporary restraining order is the same as for a preliminary injunction). In evaluating these factors, the Court should "weigh and measure each factor against the other factors and against the form and magnitude of the relief request." *Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1451 (Fed. Cir. 1988). As discussed more fully below, Plaintiffs have satisfied each of the four requirements for issuance of a temporary restraining order.

I. Plaintiffs Have a Reasonable Likelihood of Success of the Merits.

To show a reasonable likelihood of success on the merits, Plaintiffs must show that Defendants' invalidity defenses – the only defenses asserted at trial – lack substantial merit. *See Sanofi-Synthelabo*, 470 F.3d at 1374 (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239, F.3 1343, 1350 (Fed. Cir. 2001)). The Court should

evaluate this element "in light of the presumptions and burdens applicable at a trial on the merits." *Solarex Corp. v. Advanced Photovoltaic Systems, Inc.*, 1995 WL 314742, at *3 (D. Del. Jan. 6, 1995). Plaintiffs have satisfied their burden.

As set forth in great detail at trial and in Plaintiffs' post-trial brief, Defendants' invalidity arguments lack merit. Defendants' internally-inconsistent arguments – on the one hand that the invention was anticipated and obvious, but on the other hand that it was merely an unscientific "guess" – are undermined by the testimony of their own experts and the overwhelming evidence in the record. *See generally* Pls. Post-Trial Answering Br. at 18-49 ("Post-Trial Br."). Even after exhaustive fact and expert discovery, a week-long trial and extensive post-trial briefing, Defendants continue to try to have it both ways, refusing to chose between these two inherently inconsistent theories. Defendants' inability to do so undermines its invalidity defense. Also, as demonstrated at trial:

- Defendants' anticipation theory relies on the Bhasker reference, but this article (1) does not even mention Alzheimer's disease ("AD"), (2) asserts that progressive dementias (*e.g.*, AD) cannot be treated and (3) mentions galantamine only once and only for the treatment of arrested dementias (*e.g.*, tumor and local brain injuries). *See* Post-Trial Br. at 18-22.

- Defendants' obviousness theory fails to acknowledge that, as of 1986, (1) there were numerous uncertain options for treatment of AD, (2) considerable doubt existed as to the prospects of cholinesterase inhibitors to safely and effectively tread Alzheimer's disease, (3) galantamine's known pharmacological properties would have led away from its use as a treatment for AD due to its peripheral activity, lack of potency, lack of cholinergic selectivity and short duration of action, and (4) numerous objective indicia of non-obviousness exist, including long felt but unmet need, failure of others, unexpected benefits, skepticism, licensing and acquiescence and commercial success. *See* Post-Trial Br. at 22-42.

- Defendants' enablement theory fails in light of the significant evidence in the record indicating that the '318 patent claims and specification enable one of ordinary skill in the art to practice the invention and that the patent provides adequate evidence of utility. *See* Post-Trial. Br. at 42-49.

In light of these numerous and significant deficiencies in Defendants' invalidity arguments, Plaintiffs have satisfied their burden of demonstrating a reasonable likelihood of success on the merits. This is particularly true given that, as discussed *infra* (at Part III), the balance of harms weighs heavily in favor of granting the requested relief. *See, e.g., Benda v. GrandLodge*, 584 F.2d 308, 315 (9th Cir. 1978), *cert. denied* 441 U.S. 937 (1979) ("If the balance of harm tips decidedly toward the plaintiff, then the plaintiff need not show as robust a likelihood of success on the merits as when the balance tips less decidedly.").[3]

II. Plaintiffs Will be Irreparably Harmed if the Relief is Not Granted.

Plaintiffs will suffer immediate irreparable harm for which monetary damages will not suffice if Defendants launch at-risk. Although Plaintiffs arguably are entitled to a presumption of irreparable harm, *see, e.g., Eisai Co., Ltd. v. Teva Pharmaceuticals USA, Inc.*, 2008 WL 1722098 at * 10 (D.N.J. Mar. 28, 2008), such a presumption is not necessary here. As discussed at length below and in the accompanying Declaration of Christina Estabrook ("Estabrook Decl."), Plaintiffs can make a strong showing that they will be irreparably harmed if Defendants are allowed to enter the market. This harm will include, *inter alia*, delays in development projects of other products, termination of employees, price erosion and lost market share. Given the nature of this harm, monetary damages will be inadequate to make Plaintiffs whole. *See Hybritech*, 849 F.2d at 1456-57 ("It is well settled that, because the principal value of a

[3] *See also Friendship Materials, Inc. v. Michigan Brick, Inc.*, 679 F.2d 100, 105 (6th Cir. 1982 ("the likelihood of success that need be shown (for a preliminary injunction) will vary inversely with the degree of injury the plaintiff will suffer absent an injunction"); *James A. Merritt and Sons v. Marsh*, 791 F.2d 328, 330 (4th Cir. 1986) ("When the balance of harms decidedly favors the plaintiff, [plaintiff] is not required to make a strong showing of a likelihood of success...").

patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will suffice to make the patentee whole.").

A. Reduction in Development Projects and Termination of Employees

If Defendants launch at-risk, Plaintiffs will lose significant funding that has been allocated to

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See Estabrook Decl. ¶¶ 9-10. This is precisely the type of irreparable harm that is sufficient to justify preliminary relief. *See, e.g., Eisai*, 2008 WL 1722098 at *11 (finding Eisai would suffer irreparable harm because research and development projects that depended on the branded product's profits for "continued viability" were "at risk of being short circuited or shut down altogether"); *Sanofi-Synthelabo,* 470 F.3d at 1383 (listing "potential reduction in work force" among the factors sufficient to justify a finding of irreparable harm).

Plaintiffs estimate that, between the expiration of the 30-month stay and the expiration of the '318 patent on December 14, 2008,

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See Estabrook Decl. ¶ 8.

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See id. ¶ 9.

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id. ¶ 10.

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[4] **REDACTED** *See* Estabrook Decl. at n.2.

See id.

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See id.

B. Price Erosion and Lost Market Share

An at-launch risk also will irreversibly erode market price and Plaintiffs' share of the acetylcholinesterase inhibitor market. *See* Estabrook Decl. ¶ 12.

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See id. ¶ 13. Courts routinely find that this type of price erosion in the market is adequate harm to justify preliminary relief. *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (finding "irreversible price erosion in light of a complex pricing scheme that is directly affected by the presence of the generic product in the market"); *Solarex,* 1995 WL 314742, at *8 ("price erosion" is an example of the "irreparable injury that would result if preliminary injunctive relief is denied").

Plaintiffs also will suffer an immediate and dramatic reduction in market share once generic versions of RAZADYNE® IR enter the market.

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See Estabrook Decl. ¶ 13. Courts have found similar reductions in market share to be the

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[5] That fact that Plaintiffs are large companies does not reduce the harm that will be caused. *See, e.g., Eisai*, 2008 WL 1722098, *11 (noting that size of the company does not dictate whether the patentee will suffer harm that cannot be undone).

See Estabrook Decl. ¶ 11. **REDACTED**

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See id..

type of "irreparable injury that would result if preliminary injunctive relief is denied." *Solarex,* 1995 WL 314742, at *8.

III. The Balance of Harms Weigh Heavily In Favor of Granting Relief.

The balance of harms weigh heavily in favor of granting a temporary restraining order. As discussed *supra* (at Part II), Plaintiffs will suffer significant and irreparable harm if Defendants are allowed to market and sell generic versions of RAZADYNE® prior to the Court's issuance of a decision on the merits. Such an at-risk launch, even if only for a short time period, could potentially **REDACTED**

See Estabrook Decl. ¶¶ 9-10. Further,

REDACTED *See id.* ¶¶ 12-13.

In contrast, the potential harm to Defendants is *de minimis*. Particularly given the late stage of the proceedings – with trial completed and an upcoming decision on the merits – Defendants will suffer, at most, a slight delay in their ability to enter the market. As this hardship is "merely temporary in duration," it is minimal when compared to the long-term and irreversible harm that Plaintiffs will suffer by an at-risk launch. *See Kyphon, Inc. v. Disc-O-Tech Medical Technologies Ltd.*, 2004 WL 2898064, at *5 (D. Del. Dec. 10, 2004) (citing *Ortho-Pharm. Corp. v. Smith*, 15 U.S.P.Q.2d 1856 (E.D. Pa. 1990)); *Eisai*, 2008 WL 1722098, at *11 ("no leap in logic" to conclude that harm caused by temporary delay in entering the market is "substantially less" than harm to patent holder); *Solarex*, 1995 WL 314742, at *8 (hardship caused by delay of production "is not as extreme" as hardship to patent holder).

IV. Granting the Requested Relief is in the Public Interest.

The public interest also weighs heavily in favor of issuing a temporary restraining order. It is well-settled that the "public has an interest in upholding and preserving patent rights" and that these rights are "undermined when infringement is permitted during the pendency of the patent infringement action." *Solarex*, 1995 WL 314742, at *8. As the Federal Circuit explained:

> We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the 'encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.... Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts. We therefore find that the [district court] did not clearly err in concluding that the significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents' tips the scales in favor of [the patent holder's arguments regarding the public interest].

Sanofi-Synthelabo, 470 F.3d at 1383-84 (internal citations omitted); *see also Eisai*, 2008 WL 1722098, at *12 ("[T]he public benefits most from *protection* of patent rights because those who cannot afford the branded drug would not have eventual access to the generic drug if the brand manufacturer's patent were not adequately protected to ensure recovery of development costs and sufficient profit incentives.") (emphasis in original).

Here, the public interest is clearly advanced by upholding the Plaintiffs' patent rights and preventing Defendants' launch (by only a handful of days should they ultimately prevail) while the Court completes its work on a decision on the merits. Moreover, given the significant resources the Court already has devoted to this case – including conducting the trial – an at-risk launch at this late stage would greatly diminish the value of the trial and the Court's ultimate decision on the merits.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that their motion for a temporary restraining order be granted.

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